

SGLT-2 Assessment: Monotherapy and Combination Therapy

Objective – assess a drug’s comparative evidence to support price negotiations with pharmaceutical companies.

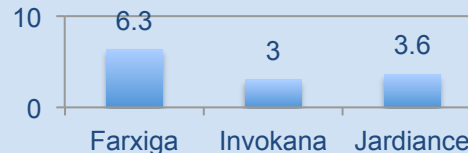
SGLT-2 drugs – Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

- Farxiga (dapagliflozin) 24-week registration trials. ¹
- Invokana (canagliflozin) 26-week registration trials. ²
- Jardiance (empagliflozin) 24-week registration trials. ³

Evidence

NNT = Number of patients you need to treat with one drug versus another drug to achieve a desired outcome. ⁴

Monotherapy Versus Placebo:
Number Needed to Treat (NNT) to
Achieve One Additional Patient
With HbA1C < 7.0



Combination Therapy With
Metformin Versus Placebo: NNT
to Achieve One Additional Patient
With HbA1C < 7.0



NNT comparison ⁵ to achieve one additional patient with HbA1C < 7.0 (average of monotherapy and combination therapy)

- Farxiga: NNT = 6.70
- Invokana: NNT = 3.75
- Jardiance: NNT = 3.70

Pricing recommendations to achieve comparable value

- Farxiga should be priced approximately 45% less than Invokana and Jardiance.
- Invokana and Jardiance should have similar pricing.

References

- 1,2,3 – FDA labels accessed 10.1.15
- 4 – <http://effectivehealthcare.ahrq.gov/glossary-of-terms/?filterletter=e>
- 5 – <http://clincalc.com/Stats/NNT.aspx?example>

Based on NNT, Farxiga’s efficacy is approximately half of Jardiance and Invokana.

- Farxiga NNT (6.70) x 55% = Jardiance NNT (3.70).
- A 45% reduction in Farxiga price will equal the value of Jardiance and Invokana.

Background Evidence



FDA Registration Trial Information

Farxiga ®

- Monotherapy: 26 week trial.
 - Placebo ® (n = 75, baseline HbA1C = 7.8)
 - Farxiga ® 10mg (n = 64, baseline HbA1C = 7.8)
 - Farxiga ® 10mg (n = 70, baseline HbA1C = 8.0)
- Metformin combo therapy: 26 week trial.
 - Metformin + placebo (n = 137, baseline HbA1C = 8.1)
 - Farxiga ® 10mg + metformin (n = 137, baseline HbA1C = 8.2)
 - Farxiga ® 10mg + metformin (n = 135, baseline HbA1C = 7.9)

Invokana ®

- Monotherapy: 26 week trial.
 - Placebo (n = 192, baseline HbA1C = 7.97)
 - Invokana ® 100mg (n = 195, baseline HbA1C = 8.1)
 - Invokana ® 300mg + metformin (n = 197, baseline HbA1C = 8.0)
- Metformin combo therapy 26 week trial
 - Placebo + metformin (n = 183, baseline HbA1C = 7.96)
 - Invokana ® 100mg + metformin (n = 368, baseline HbA1C = 7.9)
 - Invokana ® 300mg + metformin (n = 367, baseline HbA1C = 7.8)

Jardiance ®

- Monotherapy: 24 week trial.
 - Placebo (n = 224, baseline HbA1C = 7.9)
 - Jardiance ® 10mg (n = 224, baseline HbA1C = 7.9)
 - Jardiance ® 25mg (n = 228, baseline HbA1C = 7.9)
- Metformin combo therapy 26 week trial
 - Placebo (n = 207, baseline HbA1C = 7.9)
 - Jardiance ® 10mg + metformin (n = 217, baseline HbA1C = 7.9)
 - Jardiance ® 25mg + metformin (n = 213, baseline HbA1C = 7.9)

FDA Registration Trial Results

Percent of Patients Achieving HbA1C < 7.0				
Drug	SGLT-2	Average	SGLT-2 + Metformin	Average
Farxiga ®	Placebo = 32% 5mg = 44% 10mg = 51%	Placebo = 32% Farxiga ® = 48%	Placebo = 26% 5mg = 38% 10mg = 41%	Placebo = 26% Farxiga ® = 40%
Invokana ®	Placebo = 21% 100mg = 45% 300mg = 62%	Placebo = 21% Invokana ® = 54%	Placebo = 30% 100mg = 46% 300mg = 58%	Placebo = 30% Invokana ® = 52%
Jardiance ®	Placebo = 12% 10mg = 35% 25mg = 44%	Placebo = 12% Jardiance ® = 40%	Placebo = 13% 10mg = 38% 25mg = 39%	Placebo = 13% Jardiance ® = 39%